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THE LARYNGEAL MASK COMPANY LTD.
and LMA NORTH AMERICA, INC.

**IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF CALIFORNIA**

THE LARYNGEAL MASK COMPANY
LTD. and LMA NORTH AMERICA, INC.,

Plaintiffs,

v.

AMBU A/S, AMBU INC., and AMBU
LTD.,

Defendants.

AMBU A/S, AMBU INC., and AMBU LTD.,

Counterclaimants,

v.

THE LARYNGEAL MASK COMPANY
LTD. and LMA NORTH AMERICA, INC.,

Counter-Defendants.

Civil Action No. 07 CV 1988 DMS (NLS)

**PLAINTIFFS' OPPOSITION TO
DEFENDANTS' MOTION FOR
SUMMARY JUDGMENT OF
INVALIDITY FOR ANTICIPATION AND
OBVIOUSNESS**

Date: September 18, 2009

Time: 1:30 p.m.

Courtroom 10, 2nd Floor

Honorable Dana M. Sabraw

**CONFIDENTIAL INFORMATION
FILED UNDER SEAL**

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1 **I. INTRODUCTION**

2 Ambu's motion for summary judgment of invalidity of U.S. Patent No. 7,156,100 ("the
3 '100 patent") based on alleged anticipation and obviousness should be denied. Ambu invites
4 error in several ways with its analysis. Notably, Ambu applies an incorrect claim construction
5 previously rejected by this Court. Ambu also ignores its heavy "clear and convincing" burden of
6 proof, which is heightened in this case because Ambu primarily relies on prior art already
7 considered by the U.S. Patent and Trademark Office ("PTO") when it decided to grant the '100
8 patent. Likewise, Ambu oversimplifies the legal standard for obviousness, which requires
9 numerous underlying factual determinations that raise disputed issues in this case.

10 Ambu's motion is premised on an improper reading of the "thicker and stiffer" cuff wall
11 claim language. Despite this Court's claim construction ruling that the claim language has its
12 "plain meaning," Ambu now asserts that the claimed portion of a "wall of the cuff being thicker
13 and stiffer" can be met by adding some other material to the top of the posterior wall of the cuff,
14 such as an extended backplate. Ambu's attempt to rewrite the claim language and revisit the
15 claim construction is improper. The words of the claim, the specification, and prosecution
16 history all support LMA's plain meaning reading that the claimed portion of the cuff must *itself*
17 be "thicker and stiffer" than other portions of the cuff. Further, Ambu attempts to reargue a
18 proposed construction for the language that this Court already rejected, namely one in which the
19 cuff reinforcement "extends" from the backplate.

20 Ambu's case for summary judgment of anticipation fails in light of the plain meaning of
21 the claim language – neither the Brain '547 "glue filler" patent, nor the Pagan '889 "extended
22 backplate" patent disclose a cuff where a portion of the cuff wall *itself* is thicker and stiffer than
23 other cuff portions. Ambu's technical expert admitted this in deposition. Moreover, these same
24 two references were before the PTO during prosecution of the '100 patent. Ambu makes no
25 attempt to meet its added burden to demonstrate that the PTO erred in granting the '100 patent.

26 Likewise, Ambu's case for summary judgment of obviousness, which hinges on the '889
27 patent, fails on numerous grounds, including:

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- Ambu’s cited prior art fails to provide the critical link between making the cuff itself thicker versus extending the backplate.
- Ambu misrepresents the cited prior art as providing a solution to cuff foldover. Thus, a factual dispute exists regarding the “scope and content” of the prior art.
- The parties fundamentally disagree about the “level of skill in the art,” whether Ambu’s technical expert is qualified to opine on the teachings of the prior art, and how that underlying factual issue impacts the ultimate legal issue of obviousness.
- Ambu ignores the prior art that teaches away from the claimed invention, such as the prior art’s trend towards eliminating the cuff as the leading structure on insertion and its unwavering use of a uniform, pliable, and thin cuff wall thickness. There is therefore a factual dispute as to the “difference between the prior art and the claimed invention.”
- Ambu relies on prior art which was never commercialized, and which presented such severe drawbacks that it would have posed substantial risks to the patient. Thus, a factual dispute exists as to whether one of skill in the art would rely on that prior art to solve the problem of cuff foldover.
- Secondary considerations of non-obviousness, particularly long-felt but unmet need, the commercial success of Ambu’s accused products -- for which the reinforced cuff was touted as a “key feature” -- and Ambu’s failed design-around attempts, all support a finding of non-obviousness.

When the proper legal standards relating to obviousness and Ambu’s burden of proving invalidity are applied (and inferences are drawn in LMA’s favor as the non-movant) numerous factual issues preclude entry of summary judgment that the ‘100 patent claims are obvious.¹

II. STATEMENT OF RELEVANT FACTS

A. The Problem of Cuff Foldover and Absence of Solutions Prior to the ‘100 Patent

As a laryngeal mask device (“LM”) is inserted into a patient, the leading or distal end of the cuff can fold over on itself. One of LMA’s technical experts, Dr. William Rosenblatt, a practicing anesthesiologist who has used thousands of laryngeal mask airway devices, opined that this problem is often caused by a poor insertion technique. Ex. 1 at 6; Ex. 2 at 90-91 (testifying that expert reports accurately reflect his opinions).² Cuff foldover creates a variety of

¹ As a separate basis for denying Ambu’s summary judgment motion LMA has also filed herewith Plaintiffs’ Objection to Evidence in Support of Defendants’ Three Pending Summary Judgment Motions because Ambu failed to timely file and serve all of its declarations and evidence supporting these three motions and has neither sought leave of the Court to file late nor provided any basis for excusable neglect in missing the filing deadline.

² “Ex.” refers to an exhibit attached to the Declaration of John B. Sganga in Support of Plaintiff’s Oppositions to Defendants’ Motions for Summary Judgment filed herewith.

1 problems, such as: (1) a heightened risk of trauma to the patient; (2) an incomplete and
2 ineffective seal around the laryngeal inlet; and (3) an elevated risk of regurgitation of stomach
3 contents into the lungs due to the failure of the mask to properly block the esophagus. *Id.* at 6-7.

4 The '100 patent solves these problems "by incorporating into the cuff at its distal end a
5 reinforcing rib which serves to stiffen the leading end of the LMA device [during insertion]."
6 Lamp. Ex. B at col. 1:52-55.³ In one specific embodiment, the patent teaches that the
7 reinforcing rib "may be effectively constituted by a thickening of the posterior wall of the distal
8 region 60a of the inflatable main-cuff 55a...." *Id.* at col. 8:9-11. Claims 1-6 of the '100 patent,
9 all of which Ambu seeks to invalidate, relate to this thickening of the cuff wall.

10 Dr. Brain's solution to the cuff foldover problem – thickening a portion of the cuff wall –
11 was counterintuitive. The prevailing wisdom was to make the cuff wall as thin as possible, so it
12 would conform more easily to the pharyngeal anatomy and maximize the seal around the
13 laryngeal inlet. Ex. 1 at 7; Lamp. Ex. H; Brain Decl., ¶ 9; Ex. 4 at 2:15-43.

14 The problem of cuff foldover was recognized soon after Dr. Brain introduced the original
15 LM design to the marketplace in the 1980's, yet the problem was not expressly addressed until
16 1998 when Dr. Brain filed the application that issued as the '100 patent. Dr. Brain had
17 recognized the problem of cuff foldover as early as 1988, (Ex. 5 ("deflated tip is too soft to avoid
18 frequent folding over of tip on insertion into patient")), and he also described the problem in the
19 1992 Laryngeal Mask Instruction Manual, (Ex. 6). Other practitioners also recognized the
20 problem starting as early as 1990 and continuing until the time of the invention of the '100
21 patent. Ex. 7; Ex. 8 at 380 ("If the tip fails to stay flattened or the cuff begins to roll over, the
22 mask should be removed and reinserted...If resistance is felt, the tip may have folded over on
23 itself."). Likewise, other LM patents, including the Cook '860 patent, filed in 1997, discussed
24 the problem of cuff foldover. Lamp. Ex. K at col. 1:47-51 ("during insertion and positioning, the

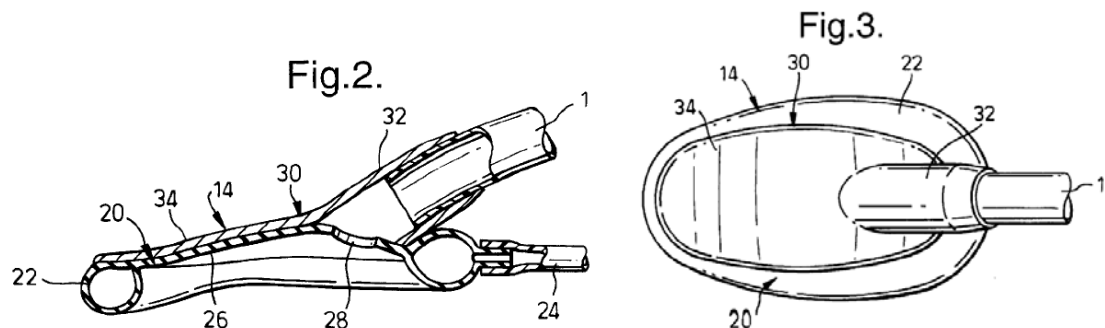
25 ///

26 ³ "Lamp. Ex." refers to exhibits attached to the Amended Declaration of Samsun
27 Lampotang, Ph.D. in Support of Defendants' Motions for Summary Judgment, belatedly filed on
28 August 17, 2009 [Doc. # 309].

flexible nature of the deflated ring structure and surrounding mask may allow the distal end of the mask to bend back on itself, preventing proper inflation and the formation of a tight seal”).

B. Unsuccessful Attempts to Solve the Foldover Problem By Others

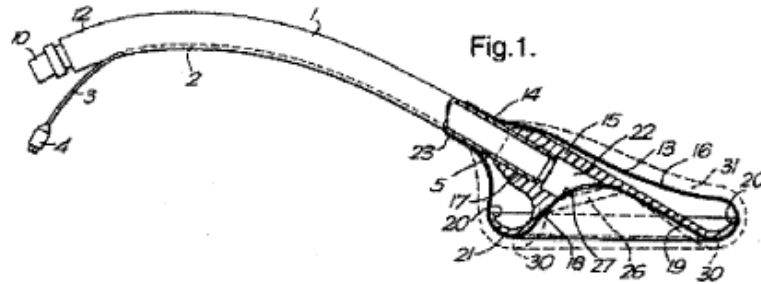
The prior art Ambu alleges solved the problem of cuff foldover in fact reflects failures to do so. The Pagan ‘889 patent did not solve “cuff foldover,” in fact it never mentions “cuff foldover.” Instead it speaks of preventing “rearward deflection,” which Pagan perceived as undesirable because the “substantially rigid” deflated cuff, when deflected rearwardly during insertion, increased the risk of trauma. Lamp. Ex. E at col. 3. Thus, Pagan ‘889 sought to resolve a different problem— one arising from the cuff being too rigid and causing trauma during insertion, rather than being so soft that it easily folds over on itself. In so doing, the Pagan ‘889 design ended up essentially eliminating the distal region of the cuff 20 by covering it with an oversized backplate 34. However, this construction results in exposing the patient to an even more rigid distal structure and makes trauma more likely during insertion, (Woo Ex. O at 18), particularly in view of the blunt shape of the leading end of the device, (Woo Ex. P at 10).



Pagan US 5,771,889 (filed 1995), Ex. E

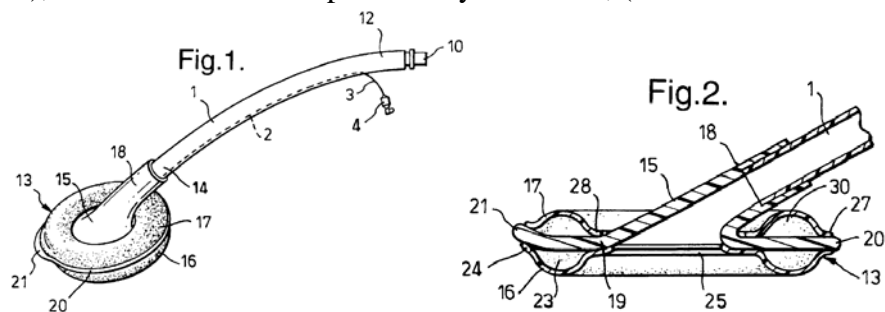
Pagan continued to work on LM designs after the unsatisfactory ‘889 patent, originally filed in 1995, and unsuccessfully tried many other approaches to modifying the leading edge of the cuff on a LM device. In a British patent application filed in 1996 (Ex. 9), Mr. Pagan extended the mount member 15 or backplate inside the cuff or bag 16, along its posterior surface. Again, the backplate overlaid the cuff and extended outward, to the periphery of the cuff. But this design, with its permanently curved leading edge, is inflexible, likely to lead to trauma, and would not effectively maintain a seal. Woo Ex. P at 13.

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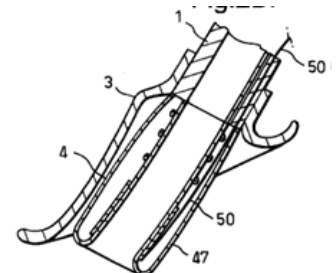
Pagan GB 2,317,830 (filed 1996), Ex. 9

Still searching for a solution, Pagan tried another approach in March 1997 when he filed a foreign application that lead to U.S. Patent No. 5,983,897. In the '897 patent, Pagan enlarged the backplate 21 even further to extend beyond the periphery of the entire inflatable cuff, as shown below. Like the prior British application, this also presented an increased trauma risk because the rigid backplate occupied an even greater portion of the leading edge of the device (Woo Ex. O at 9), and made the device particularly inflexible, (Woo Ex. P at 11-12).



Pagan '897 Patent (filed 1997), Ex. 10

Still trying to improve his designs, Pagan altered the backplate even more radically in May 1997 when he filed for what became U.S. Patent No. 6,095,144. Again the backplate 3 is the leading edge of the device, but the cuff 4 retracts entirely within the backplate. The design was so complex, it required a pull cord 50 to move the cuff into and out of position, one of its many manufacturing drawbacks. (Woo Ex. O at 10); (Woo Ex. P at 19).



Pagan '144 Patent (filed May 1997), Ex. 11

Despite years of effort, Pagan's designs were never commercialized. Ex. 13 at 146. Importantly for the purposes of this case, none of his designs featured a thickened wall of the

1 cuff itself, and instead trended in the direction of minimizing or eliminating the distal end of the
2 cuff by enlarging the backplate, at times in extreme ways. Despite these extreme differences
3 between the Pagan designs and Dr. Brain's design in the '100 patent, each of the foregoing
4 Pagan patents was relied upon by Ambu's expert as allegedly supporting a conclusion of
5 obviousness. Lamp. Ex. A at 33-34.

6 **C. Ambu Tries Various Approaches Before Arriving at Its Design with a Thickened**
7 **Cuff Wall Designed to Prevent Foldover**

8 [REDACTED]

9 [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 Ambu finally launched its first commercial product in 2004. Ex. 54 at 28-29. [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED] Ambu also prepared brochures touting the reinforced tip as helping to
19 "prevent folds during insertion that can cause improper positioning and possible airway trauma"
20 (Ex. 16), and enabling "fast and accurate positioning" (Ex. 17). Ambu also emphasized that the
21 reinforced cuff tip enabled it to use a thinner and softer cuff which forms a better seal. Ex. 16.

22 [REDACTED]

23 [REDACTED]

24 [REDACTED]

25 [REDACTED]

26 [REDACTED]

27 [REDACTED]

28 [REDACTED]

1 After LMA filed this suit, Ambu decided to remove the reinforcement from the cuff tip to
2 avoid liability. Ex. 19; Ex. 20. [REDACTED]

3 [REDACTED]
4 [REDACTED]
5 [REDACTED]
6 [REDACTED]
7 [REDACTED]
8 [REDACTED] REDACTED
9 [REDACTED]
10 [REDACTED]
11 [REDACTED]
12 [REDACTED]
13 [REDACTED]
14 [REDACTED]
15 [REDACTED]
16 [REDACTED]

17 **D. The ‘100 Patent Specification Teaches Thickening the Wall of the Cuff Itself**

18 The written description of the ‘100 patent describes a means to prevent cuff fold-over “by
19 incorporating into the cuff at its distal end a reinforcing rib which serves to stiffen the leading
20 end of the LMA-device during the course of the procedure for its insertion.” Lamp. Ex. B at
21 col.1:51-55. The ‘100 patent discloses two different methods for preventing cuff fold-over: (1)
22 reinforcing the cuff by extending the backplate through the center of the cuff, and (2) reinforcing
23 the cuff wall in the posterior region. *Id.* at col. 6:7-10, 26-33; col. 7:62, Figs. 5, 8, 10. Further,
24 the ‘100 patent describes two ways to reinforce the cuff wall in the posterior region. The two
25 ways include: (2a) applying the “distal rib of the backplate to the posterior surface of the cuff”
26 and (2b) “thickening” the cuff wall itself. [See Doc. # 137 at 6-8 (LMA’s Resp. Claim
27 Construction Br.); Doc. # 160 at slide 23 (LMA’s Claim Construction Demonstratives).]

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Specifically, the '100 patent discloses that:

“[t]he distal rib 105a *may be effectively constituted* by a thickening of the posterior wall of the distal region 60a of the inflatable main cuff 55a, and *as shown*, forms a distal extension of the bowl of the backplate 52a.”

Lamp. Ex. B at col. 8:9-12 (emphasis added). This disclosure confirms that, instead of the reinforcement necessarily being provided by an extended backplate, the reinforcement “may be” a thickened cuff wall. Indeed, the specific words chosen by the patentee are a “*thickening...of the inflatable main cuff 55a.*”

E. The Meaning To Persons of Skill in The Art of The Cuff Wall “Thickening” Description

Unlike Ambu’s purported expert, an engineer who has never used an LMA device on a patient, LMA’s technical expert Dr. William Rosenblatt is an anesthesiologist who has used thousands of laryngeal mask airway devices in his clinical practice. Dr. Rosenblatt has opined that one of skill in the art would understand the passage at Column 8, Lines 9-12 as concerning the thickening of the cuff itself:

In this embodiment, where a portion of the cuff is made thicker to provide reinforcement of the cuff, one of skill in the art would understand that the backplate structure is not being extended - the backplate ends where it is attached at its distal end to the cuff (see Fig. 3). The cuff is a separate structure providing the reinforcement (i.e. it is reinforced by itself being thicker and stiffer).

Woo Ex. O at 28; *see* Ex. 2 at 102:22-108:15.

LMA’s other technical expert, Herbert D’Alo, who has designed and manufactured laryngeal mask airway devices, has also opined and testified that the portion of the specification at Column 8, Lines 9-12 refers to the cuff itself being thicker, and not an extended backplate applied over a uniformly thin cuff. Woo Ex. P at 21-22; Ex. 27 at 61:2-64:5 (confirming accuracy of report). He has further testified that the difference in Figure 10 in the heaviness of the cross-hatching in the backplate versus the cross-hatching between the 9 o’clock to 12 o’clock position of the cuff indicates that Figure 10 did not reflect an extended backplate and of course, it does not show a backplate laid over the cuff. *Id.* at 77:25-85:12.

F. The Issued Thicker-Cuff-Wall Claims Reflect a Fundamental Shift During Patent Office Proceedings Away From Claims Involving An Extended Backplate

From the beginning of prosecution of the '100 patent’s application in 1999 until 2006, all

1 pending claims that concerned reinforcing the cuff recited a backplate/bowl structure having a
2 “distal rib.” For example, original-filed claim 1 recited “a backplate comprising a bowl...having
3 a longitudinal distal rib for longitudinally supporting the distal region of said main cuff.” Ex. 53.

4 Similarly, in October 2005, the application claims called for a “backplate having a
5 longitudinal distal rib....” Ex. 29. With these claims, the reinforcement was provided by an
6 extended backplate as shown in Figures 6 and 11 of the ‘100 patent. Those claims were rejected
7 by the Patent Office. Ex. 30. These “extended backplate” reinforcement claims were then
8 cancelled and replaced in early 2006 with claims directed to, for the first time, a “thicker and
9 stiffer” cuff wall portion. Ex. 31. The Patent Office allowed these “thickened cuff claims” and
10 they issued on January 2, 2007. Thus, the prosecution history reflects that the structure of an
11 extended backplate was not the basis for distinguishing the issued claims from the prior art, but
12 rather it was the thickened and stiffened portion of the cuff wall itself. This history counsels
13 away from reading the thickened cuff claims as including within their scope an extended
14 backplate or other overlaid structure, as Ambu argues.

15 The following table reflects the above change in the claim language, from a
16 reinforcement provided by a “backplate having a distal rib” (i.e. an extended backplate) to a
17 reinforcement provided by a cuff that is itself thicker in the distal region.

Application claim 34 (pending Oct. 2005)	Issued Claim 1
KEY BACKPLATE TERMS	
said backplate having a longitudinal distal rib for longitudinally supporting the distal region of said main-cuff.	a backplate defining a passage;
KEY CUFF TERMS	
an inflatable main-cuff . . . being a molded product of relatively thin and softly pliant elastomeric material	at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff.

25 Indeed, in the summary of the interview on May 22, 2006, the patentee distinguished the claims
26 as patentable without any reference or reliance upon an extended backplate. Ex. 33
27 (“[applicant’s representatives] pointed out that the amended claim language with the limitations
28

1 of ‘at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker
2 and stiffer than other portions of the cuff’ is readable over the Pagan reference in that the Pagan
3 reference does not disclose a rib”). This is because the patentee had already cancelled claims
4 directed to the “backplate having a distal rib” and substituted different claims – that ultimately
5 issued – which call instead for a thickened cuff wall. *Compare* Exs. 29 and 34.

6 **G. The PTO Considered the Pagan ‘889 and Brain ‘547 Patents in Deciding to Issue the**
7 **‘100 Patent**

8 Ambu claims that both the Pagan ‘889 patent and the Brain ‘547 patent anticipate all the
9 claimed features of the ‘100 patent and thus render it invalid. However, both of these prior art
10 patents were considered by the PTO and not found to be invalidating. Consideration of these
11 patents by the PTO is reflected in the list of “references cited” on the cover page of the ‘100
12 patent, which identifies both the ‘889 and ‘547 patents, as well as the European counterpart to
13 Pagan ‘889, EP 0732116. *Lamp. Ex. B.*

14 Likewise, Ambu’s obviousness argument is primarily based on the Pagan ‘889 patent,
15 either alone or in combination with other references. Yet, the PTO initially rejected the ‘100
16 patent application as obvious in view of the Pagan ‘889 counterpart, EP 0732116, referenced as
17 Pagan ‘116, which disclosed the same invention as the ‘889 patent. *Ex. 30.* In response, Dr.
18 Brain amended the claims (as discussed above) to remove reference to the *backplate* having a
19 rib, and instead specified a thicker and stiffer *cuff* wall. *Supra*, IV.F.

20 **H. Claim Construction Arguments and The Court’s Claim Construction Order**

21 During claim construction, Ambu relied upon Column 8 of the ‘100 patent to argue that
22 the claim language should be construed as “a portion of the posterior wall of the cuff where it
23 attaches to the distal end of the backplate *is thickened and stiffened by a reinforcement extending*
24 *from the distal end of the backplate.* Ambu’s underlying argument, repeated in the instant
25 motion, was that “there is simply no disclosure anywhere in the ‘100 patent of a means to
26 reinforce the cuff wall *other than by an extension of the backplate.*” [Doc. # 136 at 17.] The
27 Court rejected Ambu’s proposed construction and agreed with LMA that the claim language has

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its “plain meaning.” [Doc. # 171 at 9 (“...the Court declines to find that the “thicker and stiffer” portion must be connected to backplate”).]

III. LEGAL BACKGROUND

Under 35 U.S.C § 102, “anticipation” occurs when a single prior art reference discloses all the limitations of a patent claim and enables one of ordinary skill in the art to make and use the claimed invention; the invention is said to be anticipated and the claim is invalid. A patent claim is not anticipated when a reference is missing one or more of the claim’s limitations. *Net MoneyIN, Inc. v. VeriSign, Inc.*, 545 F.3d 1359, 1369 (Fed. Cir. 2008). Anticipation is a question of fact. *Finisar Corp. v. DirecTV Group, Inc.*, 523 F.3d 1323, 1334 (Fed. Cir. 2008).

Under 35 U.S.C § 103, a patent claim may also be found invalid if “the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains.” The Supreme Court has provided the following framework for applying the statutory language of § 103:

Under §103, the scope and content of the prior art are to be determined; differences between the prior art and the claims at issue are to be ascertained; and the level of ordinary skill in the pertinent art resolved. Against this background the obviousness or nonobviousness of the subject matter is determined. Such secondary considerations as commercial success, long felt but unsolved needs, failure of others, etc., might be utilized to give light to the circumstances surrounding the origin of the subject matter sought to be patented.

Graham v. John Deere Co. of Kansas City, 383 U. S. 1, 17-18 (1966).

Obviousness is ultimately a question of law, but the underlying issues regarding the scope and content of the prior art, differences with the claimed invention, the level of skill in the art, and the secondary considerations of non-obviousness are all factual inquiries. *Sanofi-Synthelabo v. Apotex, Inc.*, 550 F.3d 1075, 1085-86 (Fed. Cir. 2008). Evidence relating to secondary considerations constitutes independent evidence of nonobviousness and can be very instructive in the obviousness inquiry. *Sud-Chemie, Inc. v. Multisorb Techs., Inc.*, 554 F.3d 1001, 1008 (Fed. Cir. 2009) (vacating summary judgment of obviousness where the court failed to consider the secondary considerations and factual differences between the prior art and the invention).

1 While the Supreme Court's 2007 opinion in *KSR International Co. v. Teleflex Inc.*
2 instructed lower courts not to apply the so-called teaching-suggestion-motivation test in a rigid
3 manner and to exercise a common sense approach to the obviousness inquiry, it confirmed the
4 vitality of the *Graham* framework and reiterated that "a factfinder should be aware, of course, of
5 the distortion caused by hindsight bias and must be cautious of arguments reliant upon *ex post*
6 reasoning." 550 U.S. 398, 421 (U.S. 2007) (citing *Graham*, 383 U. S. at 36).

7 *KSR*'s mandate to use a "common sense" approach in an obviousness analysis, and to
8 avoid strict adherence to a "teaching, suggestion, or motivation" standard, however, does not
9 translate into a mandate to grant summary judgment of obviousness simply because individual
10 claimed elements of the patent claim can be found after scouring the prior art.

11 [A] patent composed of several elements is not proved obvious merely by demonstrating
12 that each of its elements was, independently, known in the prior art. Although common
13 sense directs one to look with care at a patent application that claims as innovation the
14 combination of two known devices according to their established functions, it can be
15 important to identify a reason that would have prompted a person of ordinary skill in the
16 relevant field to combine the elements in the way the claimed new invention does. This is
17 so because inventions in most, if not all, instances rely upon building blocks long since
18 uncovered, and claimed discoveries almost of necessity will be combinations of what, in
19 some sense, is already known. *KSR*, 550 U.S. at 419.

20 Ambu also improperly ignores whether the prior art "teaches away" from making the
21 claimed combination. When the prior art "teaches away" from the invention, such as by
22 indicating that the invention would not have worked for its intended purpose, the invention is not
23 obvious. *Depuy Spine, Inc., v. Medtronic Sofamor Danek, Inc.*, 567 F.3d 1314, 1326 (Fed. Cir.
24 2009) (affirming nonobviousness of medical device patent where prior art taught that a rigid
25 screw, like the invention at issue, was likely to fail in use).

26 Thus, Ambu's argument that the "Supreme Court changed the standards" of the
27 obviousness inquiry overstates its effect. (Ambu's Mot. at 1.) Whether there was some
28 motivation or suggestion to combine the prior art to result in the claimed invention is still a
relevant inquiry. *Lucent Techs. Inc. v. Gateway, Inc.* 509 F.Supp.2d 912, 933-934 (S.D. Cal.
2007) (denying request for new trial premised on pre-*KSR* instruction that jury "may consider
whether there was some motivation or suggestion for a skilled person to make the combination
covered by the patent").

1 Obviousness remains a factually intensive inquiry. While in *KSR* summary judgment
2 was found proper, the Court qualified that the same result was proper only where, as in *KSR*, “the
3 content of the prior art, the scope of the patent claim, and the level of ordinary skill in the art *are*
4 *not in material dispute*, and the obviousness of the claim is apparent in light of these factors,
5 summary judgment is appropriate.” *KSR*, 550 U.S. at 427 (emphasis added).

6 Ambu bears the burden of establishing invalidity by clear and convincing evidence.
7 *Lucent Techs., Inc. v. Microsoft Corp.*, No. 06-CV-0684-H (CAB), 2008 WL 4853592 at *10
8 (S.D.Cal. 2008). Moreover, “when no prior art other than that which was considered by the PTO
9 examiner is relied on by the attacker, he has the added burden of overcoming the deference that
10 is due to a qualified government agency presumed to have properly done its job, which includes
11 one or more examiners who are assumed to have some expertise in interpreting the references
12 and to be familiar from their work with the level of skill in the art and whose duty it is to issue
13 only valid patents.” *Am. Hoist & Derrick Co. v. Sowa & Sons*, 725 F.2d 1350, 1359-60 (Fed.
14 Cir. 1984). Notably, in *KSR* the obviousness attack was based primarily on prior art *not*
15 considered by the PTO. *KSR*, 550 U.S. at 411-12.

16 IV. ARGUMENT

17 A. LMA’s Plain Meaning Reading is Correct Based on the Words of the Claim Itself, 18 the Specification’s Description of Thickening the Cuff Wall, and the Patent Maxim that Claims Should be Construed to Preserve Their Validity

19 The Court has already construed the phrase “at least a portion of the posterior portion of a
20 wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff,”
21 finding that it has its plain meaning as was proposed by LMA. [Doc. # 171 at 9.] In the process,
22 the Court rejected Ambu’s proposed construction (“a portion of the posterior wall of the cuff
23 where it attaches to the distal end of the backplate *is thickened and stiffened by a reinforcement*
24 *extending from the distal end of the backplate*”) and Ambu’s underlying argument, repeated in
25 the instant motion that “there is simply no disclosure anywhere in the ‘100 patent of a means to
26 reinforce the cuff wall other than by an extension of the backplate.” *Id.*; [Doc. # 136 at 17:1-3].
27 The plain meaning of the claim language is that a select portion of the cuff wall is itself thicker
28 and stiffer and not, as Ambu erroneously argued, that the cuff wall is thickened by applying an

1 extended backplate or other material to the posterior wall of the cuff. Ambu now reargues the
2 very claim construction dispute that it lost, without presenting grounds for reconsideration.

3 Whereas Ambu argued during claim construction that the claim only covers
4 reinforcement by a backplate extending over the cuff, it now contends that

5 “a cuff wall can be reinforced, and made ‘thicker and stiffer’ within the meaning of claim
6 1, either by thickening the material of the cuff in the specific area, *or* by adhering to the
cuff another material such as glue, a rib such as is taught in the two patent drawings, or
other reinforcing material.”

7 *Compare* Doc. # 114 at 19 with Doc. # 295-2 at 11 (emphasis added).

8 Just as Ambu was incorrect that the claim language was solely limited to a reinforcement
9 based on extending the backplate, it is likewise incorrect that the claim language encompasses
10 both of these ways to reinforce the cuff.

11 **1. The claim language, specification, and prosecution history**

12 As set forth above, the claim language is “at least a portion of the posterior portion of a
13 wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff” and
14 the Court has ordered that the language has its “plain meaning.” This claim language refers to
15 the cuff itself being thicker and stiffer, and does not reference the backplate or any other
16 structure for the reinforcement (as every prior claim involving cuff reinforcement presented
17 during prosecution had, including prior claim 34, *supra* at 10).

18 The specification describes a “second embodiment” associated with direct reinforcement
19 of the posterior wall of the cuff and provides two ways for its construction: applying the “distal
20 rib of the backplate to the posterior surface of the cuff” (embodiment “2(a)”) and “thickening”
21 the cuff wall itself (embodiment “2(b)”). Specifically, the ‘100 patent discloses that “[t]he distal
22 rib 105a *may be effectively constituted* by a thickening of the posterior wall of the distal region
23 60a of the inflatable main cuff 55a, and *as shown*, forms a distal extension of the bowl of the
24 backplate 52a.” *Lamp. Ex. B* at col.8:9-12 (emphasis added). This disclosure confirms that,
25 instead of the reinforcement being provided by an extended backplate, the reinforcement instead
26 “may be” a thickened cuff wall.

27 ///

1 This passage continues that what is “shown” in the figures “forms a distal extension” of
2 the backplate. Overall, this passage conveys that there may be a thickened cuff wall embodiment
3 (2(b)) that is not comprised of a cuff wall plus overlaid backplate. Indeed, the description at
4 Column 8, lines 9-12 (“the distal rib 105a may be effectively constituted by a thickening of the
5 posterior wall of the distal region...”) would be superfluous if it also described, as Ambu
6 contends, an extended backplate. Instead, the sentence uses the precise words “*a thickening...of*
7 *the inflatable main-cuff 55a*” to describe a portion of the cuff that is itself thicker and stiffer than
8 other portions of the cuff. This would not be the case if the backplate was extended over and
9 applied to the cuff wall.

10 Ambu complains that the thickened cuff wall was not illustrated in any of the figures.
11 However, while the Summary of the Invention describes the “present invention” in terms of a
12 reinforcement “incorporated into the cuff,” a device having an “extended backplate” was
13 identified as a “preferred aspect.” Lamp. Ex. B at col. 1:52-67. It is not unreasonable therefore
14 for the specification’s figures to have illustrated designs having the extended backplate of the
15 preferred design. The claims can nonetheless encompass a described, but not illustrated,
16 embodiment. *Nazomi Commc’ns., Inc. v. ARM Holdings, PLC*, 403 F.3d 1364, 1369 (Fed.Cir.
17 2005) (claims may embrace “different subject matter than is illustrated in the specific
18 embodiments in the specification”).

19 At best, Ambu can only argue that a greater portion of the specification was focused on
20 reinforcement of the cuff by extending the backplate as a solution to preventing cuff foldover.
21 However, it is well settled that limitations should not be read into otherwise unrestricted claims
22 based on the primary focus of the patent’s solution to the problem. *Sunrace Roots Enter. Co.,*
23 *Ltd. v. SRAM Corp*, 336 F.3d 1298, 1305 (Fed. Cir. 2003) (“while it is clear that the patentee was
24 primarily focused on an embodiment of his invention using a cam, nothing in the patent limits
25 the claims to that embodiment.”).

26 Finally, the prosecution history reflects a shift in the claims away from those specifying a
27 reinforcement using an extended backplate to the issued claims requiring that a portion of the
28

1 cuff itself be thicker and stiffer. It was these latter claims which were allowed, and Ambu cannot
2 now rewrite the issued claims to encompass the previously rejected “extended backplate” claims.

3 **2. Both parties’ experts have testified that the claim language is not met**
4 **by an extended backplate**

5 Ambu is correct that LMA’s experts have opined and testified that in their view, one of
6 ordinary skill in the art would understand that the “thicker and stiffer” cuff wall claim limitation
7 requires that a portion of the cuff itself be thicker and stiffer than other portions of the cuff.
8 (Ambu’s Mot. at 11). Ambu also cites some testimony from one of LMA’s experts that it argues
9 supports its interpretation that the “thicker and stiffer” claim language can be met by an extended
10 backplate or overlaid material. *Id.* However, Mr. D’Alo did not adopt Ambu’s hypothetical
11 about a conference room wall being thickened by gluing of a sheet of plywood to it⁴ and
12 correctly confirmed that the patent claim language does not contains words of exclusion or
13 preclusion as to particular manufacturing methods, such as injection-molding technology or
14 blow-molding technology. Critically, in none of the testimony did LMA’s experts state that the
15 claimed “thicker and stiffer” portion of the cuff could be practiced by an overlaid backplate or
16 other material affixed to the posterior surface of the cuff.

17 However, consistent with the testimony of LMA’s expert witnesses, Ambu’s own expert
18 admitted that a backplate that extends over the posterior wall of the cuff does not fall within the
19 scope of the “thicker and stiffer” cuff wall claim language. Specifically, in discussing the ‘889
20 patent, Prof. Lampotang conceded that the extended backplate of that reference did not meet the
21 claim limitation, because it did not “literally have a thicker cuff wall.” Ex. 13 at 66:9-14; *see id.*
22 at 104-105 (identifying three alleged “anticipating” prior art references, but not including the
23 ‘889 patent). Thus, even Ambu’s expert does not interpret the ‘100 patent claim language to
24 cover a separate reinforcing structure such as an extended backplate that overlays the posterior
25 wall of the cuff in the distal region.

26 ⁴ “Well, the analogy of the plywood to the wall is somewhat misleading. When
27 you say put a piece of plywood on the wall, you add a component but you haven’t changed the
28 wall underneath. The plywood on the surface is still a piece of plywood.” Ex. 27 at 88:18-23.

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3. **The claims should be construed to preserve validity**

Finally, LMA's reading of the claim language preserves the validity of the claim. In contrast, to the extent Ambu's construction supports a finding of anticipation, that would conflict with the PTO's decision to issue the '100 patent after considering the '889 reference. Given the opportunity to adopt LMA's narrower claim construction preserving validity, the Court should adopt it. *Athletic Alternatives, Inc. v. Prince Mfg., Inc.*, 73 F.3d 1573, 1581 (Fed. Cir. 1996).

For the reasons set forth above, LMA submits that the plain and ordinary meaning to one of skill in the art of the claim limitation "at least a portion of the posterior portion of a wall of the cuff in the distal region being thicker and stiffer than other portions of the cuff" is that a portion of the cuff wall is *itself* thicker and stiffer than other portions of the cuff wall.

B. The '100 Patent Claims Are Not Anticipated

1. **The '547 patent shows a glue filling, not a thicker and stiffer cuff wall**

Dr. Brain's U.S. Patent No. 5,297,547 ("547 patent") does not disclose a cuff wall which itself is thicker and stiffer. *See* Lamp. Ex. G. Rather, as Ambu concedes, the '547 shows a "glue layer" on top of both the backplate and the cuff. (Ambu's Mot. at 12.) Ambu improperly infers that the "glue layer makes a portion of the cuff wall . . . thicker." (*Id.*) However, if the glue layer were to transform into some other structure, as Ambu posits, then Ambu fails to explain why the glue should become the cuff wall, as opposed to becoming the backplate, which the glue also overlays. If the glue is part of the backplate, then the '547 patent is essentially an extended backplate design like the Pagan prior art that LMA successfully distinguished in the PTO proceedings. Ambu thus is improperly drawing inferences in its favor.

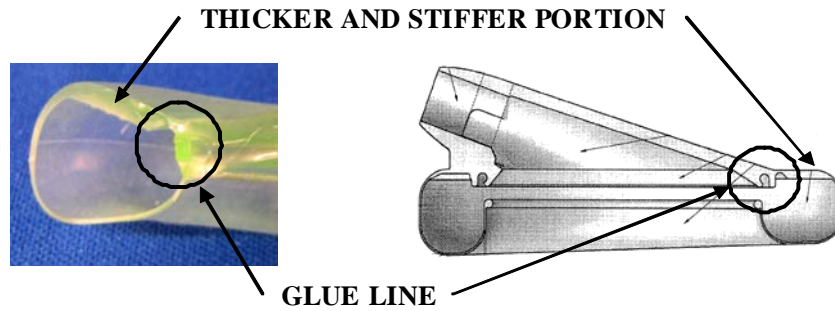
LMA's expert, Mr. D'Alo, explained that making the cuff thicker and stiffer is different than adding glue to the cuff, as "that's not changing the cuff itself." Ex. 27 at 67-68. Likewise, Dr. Rosenblatt opined that the '547 lacked any reference to making the cuff wall thicker and stiffer, and that the glue filler is a "separate structure" designed to allow the deflated cuff to assume an upturned shape. Woo Ex. O at 6-7.

Ambu cannot and does not identify any disclosure in the '547 patent about preventing cuff foldover because none exists. Nor does the '547 state that the glue filler actually stiffens the

1 cuff. Ambu points to text from a claim in the ‘547 patent which mentions “body stiffness,”
2 (Lamp. Ex. G at col. 5:13), but “body” refers to the backplate, not the cuff, and the claim does
3 not indicate how that “stiffness” compares with the cuff’s normal thickness. Ambu overlooks
4 the next few lines of text in the ‘547 that refer to the deflated cuff (ring) forming a “resilient”
5 concave flange for “resiliently loaded” sliding contact. *Id.* at col. 5:13-23. The ‘547 earlier
6 explains that the thickness of the glue filler “gradually reduces in the distal direction, whereby to
7 enhance the resilience of the distal end of the body.” Lamp. Ex. G at 2:66-68. Thus, the ‘547
8 explicitly discloses making the distal end of the cuff more resilient, not stiffer. The ‘547 does
9 describe forming the deflated cuff into a “concave” or “upturned” shape, while pointing out that
10 the cuff remains “softly yieldable.” *Id.* at col. 1:47-50. But the ‘100 patent repeatedly refers to
11 the reinforcing rib creating a “downturned profile.” Lamp. Ex. B at col. 2:10-11, 8:12-15.

12 The ‘547 patent was considered by the PTO, and though it initially formed the basis for
13 five different rejections by the PTO, ultimately the claims in the ‘100 patent were re-written to
14 overcome the rejections. Ex. 34. The ‘547 is also described in U.S. Pat. No. 5,305,743, (Ex. 4)
15 which itself describes a glue filler or bead 42, and is incorporated by reference into the ‘100
16 Patent at column 7, line 47. The ‘743 patent, in turn, characterizes the application that became
17 the ‘547 patent as disclosing a filler that “aids in the desired collapse of [cuff] 13 when
18 evacuated for ease of insertion . . .” Ex. 4 at 6:52-55. Again, there is no mention of the glue
19 providing stiffness so as to prevent foldover during insertion, but rather only to initially orient
20 the deflated cuff in a desired shape before insertion.

21 Finally, Ambu’s broad reading of the “thicker and stiffer cuff wall” limitation to cover
22 the glue joint between the cuff and backplate is inconsistent with LMA’s application of the
23 claims for infringement purposes. The Ambu products have a glued joint between the cuff and
24 backplate (below). While this joint is analogous to the glue filling in the ‘547 patent, the joint is
25 distinct from the V-shaped reinforcement that LMA contends is the thicker and stiffer wall
26 portion. Thus, Ambu improperly stretches the claim beyond the Court’s construction, and
27 beyond LMA’s application of that construction, in its attempt to make the ‘547 patent anticipate.
28



In view of these disputed issues, summary judgment of anticipation based on Brain ‘547 patent would not be proper.

2. The ‘889 patent has an extended backplate, not a thickened cuff wall

Ambu’s argument that the extended backplate of Pagan ‘889 “becomes part of the cuff wall” (Ambu’s Mot. at 15:19), is fundamentally flawed.⁵ The backplate and the cuff are distinct elements both physically and as claimed. *Stumbo v. Eastman Outdoors, Inc.*, 508 F.3d 1358, 1362 (Fed. Cir. 2007) (adopting a construction that would give “each claim term . . . a distinct meaning” to avoid improper “superfluous” terms). Ambu’s attempt to conflate the two structures is illogical and inconsistent with both: (1) its own expert, who admitted that Pagan ‘889 does not “literally” have a thicker cuff wall (Ex. 13 at 64:9-14 (Lampotang Dep. Tr.)); and (2) the PTO proceedings in which LMA overcame rejections based on Pagan ‘889 by claiming a thicker cuff wall, as opposed to an extended backplate. [Dkt. # 114-2, Exs. M, N, O.]

Ambu’s suggestion that Mr. D’Alo agreed with Ambu’s position is misleading. He testified that a backplate extension would make “the assembly stiffer” but that was “not changing the cuff wall itself.” Ex. 27 at 67:20-68:8. The claim calls for a thickened cuff wall, not a thickened “assembly.” Whether one could hypothetically add more layers onto the claimed thickened cuff is inconsequential for two reasons. First, Ambu’s accused devices do not include a separate layer that is added on to its physically thickened cuff. Second, it is axiomatic that adding unclaimed structure to an infringing device does not avoid infringement. *CIAS, Inc. v.*

⁵ LMA does not concede that Pagan ‘889 includes all of the other claim limitations, but addresses only the disputed factual issues on the “thickened cuff wall” limitation since that alone is sufficient to preclude summary judgment.

1 *Alliance Gaming Corp.*, 504 F.3d 1356, 1360 (Fed.Cir. 2007) (“In the patent claim context the
2 term ‘comprising’ is well understood to mean ‘including but not limited to.’”)

3 Finally, Ambu cannot meaningfully identify where the “distal region” of the cuff is in
4 Pagan ‘889. That is critical since the thicker and stiffer portion must be in that “distal region.”
5 At Ambu’s urging, the Court construed “distal region” to be “distal to the backplate, i.e., the
6 leading edge of the cuff.” [Doc. # 171 at 8:6.] In Pagan ‘889, there is little if any cuff located
7 distal to the extended backplate, and what is there is unreinforced. Ambu wants the backplate to
8 extend out and become one with the cuff when Ambu wants a thickened cuff, meanwhile
9 pretending that the backplate can be pulled back to no longer overlay the cuff when Ambu wants
10 to delineate a distal region. Ambu cannot have it both ways – the Pagan ‘889 reference simply
11 lacks a thickened portion in the distal region of the cuff. Thus, genuine factual disputes
12 preclude summary judgment of anticipation.

13 **C. The ‘100 Patent Claims Are Not Obvious**

14 Ambu’s attempt to analogize this case to *KSR* is misplaced. Ambu relies simply on the
15 alleged presence of individual elements in the art (which is disputed), and fails to present
16 uncontroverted evidence of “a reason that would have prompted” a combination to result in the
17 claimed invention. *KSR*, 550 U.S. at 419. In *KSR*, the invention related to adding an electronic
18 position sensor to an adjustable accelerator pedal for a car. All of the claimed elements were
19 known in the prior art, and in some instances were designed as off-the-shelf, one-size-fits-all
20 components. *Id.* at 409 (“A modular sensor is designed independently of a given pedal so that it
21 can be taken off the shelf and attached to mechanical pedals of various sorts . . .”). Moreover,
22 the Patent Office was not aware of all of those pieces when allowing the patent in suit. *Id.* at
23 412. (The prior art patent to “Asano was not mentioned in the patent’s prosecution. Thus, the
24 PTO did not have before it an adjustable pedal with a fixed pivot point.”).

25 In contrast, here all the prior art which forms the basis for Ambu’s obviousness attack is
26 missing a key piece of the puzzle – a thickened LM cuff wall. Even if the thickened cuff wall
27 were known in the prior art, the claimed element of the laryngeal mask is not a modular, off-the-
28 shelf, mix-and-match component. Ambu cannot meet its heavy burden by combining references

1 that do not clearly disclose thickened cuff walls with other references that would need multiple
2 design changes to result in the claimed invention. Ambu provides no reason that one of skill in
3 the art would have been prompted to make the combinations and modifications that Ambu
4 suggests, other than through impermissible hindsight. At a minimum, factual disputes preclude
5 summary judgment on obviousness.

6 **1. The appropriate level of skill in the art**

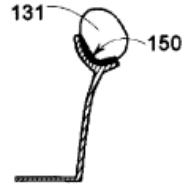
7 Ambu simply ignores this foundational issue – obviousness is judged through the eyes of
8 a person of ordinary skill in the art. *KSR*, 550 U.S. at 406-07. The parties disagree on this issue,
9 notably regarding the proper amount of clinical experience actually inserting airway devices into
10 patients. *Compare* *Woo Ex. O* at 20 with *Amended Lampotang Decl.* at 3. Conveniently,
11 Ambu’s expert, who has no experience himself inserting LM devices in patients (*Ex. 12* at
12 39:13-24), has defined the level of skill to include general anesthesia training, but not specific
13 training or experience either inserting airway management devices or working closely with those
14 who do. Ambu fails to present evidence of obviousness through the eyes of one having the
15 proper skill level, giving rise to yet another factual dispute.

16 **2. The Pagan ‘889 patent in combination with the Hoftman ‘094 patent**

17 Ambu’s premise is that one of skill would start with the Pagan ‘889 patent and then
18 modify it to eliminate the extended backplate and instead incorporate a truly thickened cuff wall.
19 This requires several logical steps by the person of ordinary skill: 1) an insight to disregard
20 Pagan’s teaching to use a wide, blunt, rigid backplate at the distal end of the device; 2) a general
21 inspiration to thicken the cuff from some other prior art (none of which used a thickened distal
22 region of a cuff as the leading edge for an LM device); 3) and an insight to modify the Pagan
23 ‘889 device in two distinct ways, first by shortening the backplate to expose the cuff, and second
24 to thicken the cuff only in the now-exposed posterior region. *Ex. 13* at 74-75.

25 Ambu first suggests these steps would have been inspired by the Hoftman ‘094 patent
26 (*Lamp. Ex. I*), which discloses a face mask that is not inserted into a patient’s airway, and thus
27 does not address cuff foldover. *Lamp. Ex. P* at 20. Assuming Figure 10 (below) of the ‘094
28 patent shows a thickening 150 where the inflatable cuff 131 joins the mask for purposes of

1 gluing the two together (Lamp. Ex. I at 8:26), Ambu presents no reason
2 why the person of skill would think to leap from that design to a thickened
3 portion of the leading portion of a cuff in an LM device, which could
4 potentially cause increased patient trauma.



5 Ambu cannot meet its burden of proving obviousness by simply stating that people knew
6 how to manufacture a thicker cuff wall. The invention in the '100 patent is not directed to a
7 manufacturing technique.

8 **3. '889 in combination with the Brain 1991 article**

9 Ambu's attempt to combine the Pagan '889 and the Brain 1991 article fails for similar
10 reasons. The most Ambu's expert derives from the article in terms of suggesting a modification
11 to Pagan '889 was that Brain 1991 showed that "controlling the thickness of the cuff was
12 known." Ex. 13 at 62:15. But *KSR* counsels that merely finding the pieces of the puzzle in the
13 prior art does not mean it was obvious to combine them as claimed – Ambu failed to show how
14 the person of skill would be motivated to make the modifications needed.

15 Moreover, Ambu's analysis assumes that the Brain 1991 article taught the selective
16 thickening of a cuff wall, which it does not. Brain Decl. ¶ 7. As explained by Dr. Brain, the
17 1991 article describes several different LM devices made by different manufacturing techniques.
18 Rather than discussing thickening the cuff selectively, the article explains the benefit of having a
19 thin distal leading end of the cuff. Brain Decl. ¶¶ 9-13. Dr. Lampotang conceded that "it was
20 not clear" whether the 1991 article disclosed making the cuff "thinner or thicker." Ex. 13 at 69-
21 70 (Lamp. Dep. Tr.). Nonetheless, he chose to interpret it as making the cuff thicker, yet another
22 inference drawn in Ambu's favor. *Id.* at 69:24. Similarly, Dr. Lampotang also acknowledged
23 that "it's hard to tell" whether the 1991 article discusses cuff foldover. *Id.* at 70:5 - 72:16. A
24 factual dispute remains regarding the scope and content of the 1991 Brain article, and whether
25 there would have been any motivation to combine its thin leading cuff with the Pagan '889
26 reference's extended backplate design.

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1 **4. Pagan ‘889 in combination with known manufacturing techniques**

2 Ambu’s argument regarding known manufacturing techniques points out the deficiencies
3 with its obviousness analysis. It is not enough to know generally how to make a cuff thicker.
4 Ambu simply assumes that a person of skill “wanted to make a reinforced cuff” having the
5 claimed features. (Ambu’s Mot. at 19:15.) The assumption in this analysis demonstrates the
6 lack of motivation from the art to make the claimed combination.

7 **5. The operation of LM devices with modified distal ends is not**
8 **predictable**

9 Ambu also concludes that thickening the cuff wall would be a “predictable variation.”
10 But the interaction between the LM device and the patient presents several unpredictable
11 variables that affect performance of modifications to the leading edge of the cuff, namely: 1)
12 variations in the patient anatomy against which the cuff wall slides during insertion (Woo Ex. O
13 at 22); 2) variations in insertion techniques by clinicians, *id.* at 24; 3) variability in how deflated
14 the cuff is during insertion, (Ex. *14 at 73); and 4) lack of feedback, since even when inserting
15 an LM device in a manikin, it is difficult to tell if there is a foldover problem since “we can’t see
16 what’s going on” (Ex. 12 at 39:16-40:10).

17 This unpredictability is magnified by the serious consequences of the cuff folding or
18 bending in an unwanted way, including trauma to the patient, and a poor seal which could allow
19 stomach contents to enter the patient’s lungs. Ex. 1 at 7; Lamp. Ex. E at col. 1:40 (risk of
20 trauma, morbidity, and the mask entering the nasal passage). Therefore factual disputes exist as
21 to the predictability of the result of the combination Ambu claims was obvious.

22 **6. The prior art that teaches away from thickening and stiffening the**
23 **distal end of the cuff itself**

24 The prior art directed persons of skill in two very divergent ways, neither pointing to the
25 claimed invention. Pagan’s work, described above, demonstrated a strong trend toward making
26 a rigid backplate the prominent feature at the leading end of the device. Dr. Brain’s prior work
27 taught using a uniformly thin and pliable cuff as the leading edge. Lamp. Ex. H at 10 (describing
28 benefits of cuff that “could be deflated to form wafer-thin leading edge.”); Brain Decl. at ¶ 9; Ex.
4 at col. 2:15-45 (“It is desired that the wall of [the cuff] be uniformly thin,” noting problems

1 occurring from cuff wall thickness variations, and the desirability of avoiding “a relatively thick
2 wall” since it is “less compliant in adapting itself to the contours of the human” anatomy.);
3 Lamp. Ex. G at col. 2:66-68 (describing design to “enhance the resilience of the distal end of the
4 body.”) Ambu pays no heed to these trends, which both teach away from the ‘100 patent’s
5 solution of combining a soft cuff with an integral reinforced portion.

6 **7. Claims 3 and 4 relating to the “rib” are not anticipated or obvious**

7 Ambu’s reliance on the cited Brain ‘547 patent to prove obviousness is improper with
8 respect to Claims 3 and 4 in view of the same shortcomings of that patent discussed above.
9 Ambu seeks to combine the ‘547 with the Silverlock ‘858 patent, which relates to catheters, not
10 LM devices. Lamp. Ex. J. As explained by Dr. Rosenblatt, references like this relating to
11 devices from outside the supraglottic airway field are not sufficiently related to the LM field to
12 be considered as prior art. Woo Ex. O at 16.

13 Even when considered, the Silverlock patent differs from the LM device claimed, e.g.,
14 the inflatable portion of the Silverlock catheter device does not form the leading edge of the
15 catheter during insertion, there is no backplate, and no foldover issue. Woo Ex. P at 20.

16 **8. Claims 2, 5 and 6 are not anticipated or obvious**

17 Ambu presents only conclusory statements about the features of the remaining dependent
18 claims being shown in the prior art. Even if Claim 1 were anticipated by the prior art, Ambu
19 must do more to prove its defense on summary judgment than merely assert it is entitled to win.

20 **9. Ambu has failed to address the secondary considerations of long-felt
21 need; failed attempts, commercial success**

22 The efforts by others to solve the lingering problem, their unsuccessful results, and
23 Ambu’s commercial success upon its infringement all support a conclusion of non-obviousness.
24 *See supra* II.C; Woo Ex. O at 23-26. Ambu simply ignores this evidence. Instead, Ambu cites
25 two cases in which the secondary considerations were not strong enough to overcome the
26 primary evidence, and extrapolates to suggest that secondary considerations are never relevant.
27 (Ambu’s Mot. at 22.) Despite Ambu’s suggestion that analyzing secondary considerations is
28 futile, one case it cites, *Richardson-Vicks Inc. v. Upjohn Co.*, 122 F.3d 1476, 1483 (Fed. Cir.

1 1997), notes that in some cases, secondary consideration “evidence is the most probative of
2 obviousness,” and must always be considered.

3 In particular, Ambu cannot ignore the commercial success of its own infringing products.
4 The commercial success of a device embodying the claimed invention supports the non-
5 obviousness of the invention if “the sales were the direct result of the unique characteristics of
6 the claimed invention.” *In re DBC*, 545 F.3d 1373 (Fed. Cir. 2008). [REDACTED]

7 [REDACTED]

8 [REDACTED]

9 [REDACTED] REDACTED [REDACTED]

10 [REDACTED]

11 [REDACTED]

12 [REDACTED]

13 [REDACTED]

14 [REDACTED]

15 [REDACTED]

16 [REDACTED]

17 [REDACTED]

18 [REDACTED]

19 V. CONCLUSION

20 Ambu’s motion for summary judgment of anticipation and obviousness does not establish
21 an absence of genuine issues of material fact, particularly when viewed in light of Ambu’s
22 burden of proving invalidity by clear and convincing evidence, the fact that Ambu relies
23 primarily on prior art that was carefully considered by the PTO in deciding to grant Dr. Brain’s
24 ‘100 patent, the prior art as a whole, and the requisite secondary considerations. Ambu’s motion
25 should be denied.

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Respectfully submitted,
KNOBBE, MARTENS, OLSON & BEAR, LLP

Dated: August 28, 2009

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1 **CERTIFICATE OF SERVICE**

2 I hereby certify that on August 28, 2009, I caused the foregoing **PLAINTIFFS'**
3 **OPPOSITION TO DEFENDANTS' MOTION FOR SUMMARY JUDGMENT OF**
4 **INVALIDITY FOR ANTICIPATION AND OBVIOUSNESS** to be electronically filed with
5 the Clerk of the Court using the CM/ECF system which will send electronic notification of such
6 filing to the applicable registered filing users.

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18 I declare that I am employed in the office of a member of the bar of this Court at whose
19 direction the service was made.

20 Dated: August 28, 2009

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